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Prevention, Pesticides
and Toxic Substances
(7508P)

September 2008

Reregistration Eligibility Decision for d-Phenothrin

September 2008

Reregistration Eligibility Decision

for

Phenothrin

List A

Case No. 0426

Reregistration Eligibility Decision (RED) Document
For Phenothrin

Approved by: _____
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Date: 9/25/08

Glossary of Terms and Abbreviations

ae	Acid Equivalent
ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EIIS	Ecological Incident Information System
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NDETF	Non-Dietary Exposure Task Force
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts per Billion
PPE	Personal Protective Equipment
PHED	Pesticide Handler's Exposure Data
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
RfD	Reference Dose
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient

UV	Ultraviolet
UF	Uncertainty Factor
UF_{DB}	Uncertainty Factor, Database
WPS	Worker Protection Standard

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I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data to the EPA.

Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of d-phenothrin, hereinafter referred to as phenothrin. This review is being conducted to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. As a result of this review, EPA has determined that all products containing the active ingredient phenothrin are eligible for reregistration provided that the risk mitigation measures indicated in this document are adopted.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxicity mechanism could lead to the same adverse health effects as would occur at a higher level of exposure to any of the substances individually. Phenothrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying normal biochemistry and physiology of nerve membrane sodium channels, available data show that there are multiple types of sodium channels and that these compounds may act on different isoforms of the sodium channel and with other ion channels in producing their clinical signs.

It is currently unknown whether the pyrethroids as a class have similar effects on all nerve channels or whether modifications of different types would have cumulative effect. The Agency also does not have a clear understanding of effects on key downstream neuronal function, e.g. nerve excitability, or how these key events interact to produce their specific

patterns of neurotoxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding. Therefore, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because the Agency has determined further study is needed regarding the assumptions of dose additivity and common mechanisms of toxicity to appropriately identify a research group or subgroups for such an assessment. There is ongoing research by EPA's Office of Research and Development and by the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. When available, the Agency will evaluate this research and make a determination of common mechanisms as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents EPA's revised human health and ecological risk assessments and the reregistration eligibility decision for phenothrin. Section I, the introduction, contains the regulatory framework for reregistration; Section II provides an overview of the chemical, including a profile of its use and usage; Section III provides an overview of the health and environmental risk assessments; Section IV presents the Agency's reregistration eligibility, and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and data call-in (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available in the public docket under docket number EPA-HQ-OPP-2008-0140.

II. Chemical Overview

A. Regulatory History

Phenothrin was first registered by the EPA in 1976. There are currently 198 active registrations for phenothrin products.

In 2006, MGK requested a Section 3 registration for the use of phenothrin over agricultural lands to control flying mosquitoes. (There is currently one Section 18 Emergency Exemption for the use of phenothrin as a mosquitocide in California over the food/feed crops almonds, walnuts, pasture lands, and rice.) The applicant requested that the use be considered a non-food use and therefore did not petition for tolerances for residues of phenothrin in food/feed crops. EPA concluded, however, that the requested application is a food use which requires the establishment of a 0.01 ppm tolerance on all crops. MGK has subsequently petitioned the Agency for establishment of a tolerance of 0.01 for the proposed new use (petition No. 7F7251). The proposed tolerance is not established in this reregistration eligibility decision for phenothrin, but will be the basis of a separate Agency decision on a new use application. However, the human health risk assessment completed for the RED includes this pending new use.

B. Chemical Identification

Phenothrin is a pale yellow to brown (or colorless) clear liquid with a faint characteristic odor. Its reported solubility is very low (<9.7 µg/L @ 25°C). It has a low vapor pressure (1.43×10^{-7} mm Hg @ 21°C), and a calculated Henry's Law Constant of 6.80×10^{-6} atm-m^3/mol. The octanol/water partition coefficient for phenothrin is 1.03×10^{6} (log K_{OW}=6.01).

Common Name: Phenothrin (d-Phenothrin)

Chemical Name: (3-phenoxyphenyl) methyl (1R)-cis-trans-2,2-dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate

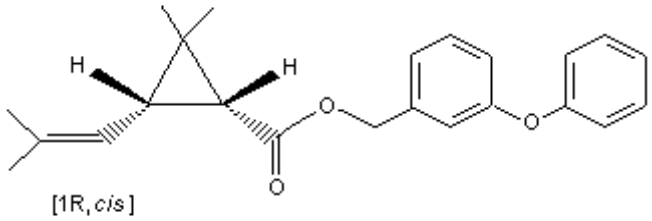
Chemical Abstracts Service (CAS) Registry Number: 26002-80-2

OPP Chemical Number: 069005

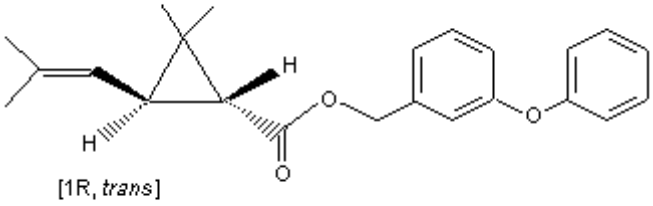
Common Trade Name: Sumithrin

Basic Manufacturers: Sumitomo Chemical Company, Ltd., McLaughlin Gormley King Company also holds technical registrations.

Chemical Structure



[1R, *cis*]



[1R, *trans*]

Chemical Family: Type 1 first-generation synthetic pyrethroid

Empirical Formula: $C_{23}H_{26}O_3$

Case No.: 0426

Molecular Weight: 350.46 g/mol

Table 1. The Physicochemical Properties of Phenothrin	
Parameter	**Value**
Melting Point/Range	Not Applicable/Technical AI is a liquid
pH	5.16 at 20 ºC
Density	1.060 specific gravity at 20 ºC
Water solubility	< 9.7 µg/L at 25 ºC
Solvent solubility	>4.96 g/mL in hexane at 25 ºC >5.0 g/mL in methanol at 25 ºC
Vapor Pressure	1.04×10^{-7} mm Hg at 21 ºC
Disassociation Constant (pKa)	Not available
Octanol/water partition coefficient, Log (K_{ow})	log P_o = 6.76 at 25 ºC log P_o = 6.01 at 20 ºC
UV/Visible Absorption spectrum	Not available

C. Use Profile

Type of Pesticide: Phenothrin is a type I synthetic pyrethroid insecticide. The synthetic pyrethroids are a class of chemical insecticides made to mimic the insecticidal properties of pyrethrins. Phenothrin is often formulated with piperonyl butoxide (or PBO), a synergist which increases the effectiveness of phenothrin as an insect knockdown agent.

Summary of Use: Phenothrin is an insecticide used in commercial and industrial settings, in animal kennels (as a spray), medical institutions, and other institutional settings. Phenothrin is formulated for use in greenhouses, homes, and gardens, and in recreational areas. Additionally, phenothrin has public health uses, specifically its use for vector control for mosquitoes. It is formulated both for indoor and outdoor use for mosquito control. Phenothrin is also formulated for use as spray-on and spot-on treatments for pets and pet quarters.

Formulation Types: Phenothrin is available as a ready-to-use (RTU) indoor spray and carpet powder, pressurized concentrate, emulsifiable concentrate, and is formulated for use in pet spot-on and stripe-on flea and tick treatments. Formulations for pet use often contain other active ingredients in addition to phenothrin. Phenothrin is also formulated for use with ultra-low volume (ULV) sprayers and indoor foggers.

Target Pests: Phenothrin targets ants, aphids, bed bugs, bees, beetles, billbugs, box elders, borers, cockroaches, cadelles, caterpillars, centipedes, crickets, daubers, earwigs, fleas, flies, gnats, hornets, crawling insects, flying insects, grain insects, lace bugs, leafhoppers, leaf miners, lice, moths, mites, mealy bugs, midges, millipedes, mosquitoes, rust, scab, scales, scorpions, silverfish, spiders, sow bugs, thrips, ticks, wasps, waterbugs, weevils, worms, and yellow jackets.

Mode of Action: Phenothrin works upon physical contact with an insect or after ingestion. Phenothrin is a nerve stimulant which forces the sodium channels of insects to remain open beyond their normal timing thresholds, causing repetitive action inside the nerve channels and eventual paralysis.

D. Estimated Usage of Pesticide

The Agency currently lacks statistics on the estimated nationwide use (in pounds) of phenothrin. In all likelihood, the nationwide use of phenothrin has greatly increased over the past five years as pyrethroid insecticide alternatives have emerged to take the place of the several organophosphate pesticide residential uses that are no longer available.

III. Summary of Phenothrin Risk Assessments

The following is a summary of EPA's human health and ecological risk findings and conclusions for phenothrin, as presented fully in the documents:

- *Phenothrin Revised Risk Assessment,* dated July 2, 2008
- *Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision*, dated July 2, 2008
- *Phenothrin (d-Phenothrin) Acute and Chronic Dietary and Drinking Water Exposure and Risk Assessment for the Reregistration Eligibility Decision*, dated February 6, 2008
- *Environmental Fate and Effects Science Chapter for the Reregistration Eligibility Decision of Phenothrin*, dated March 5, 2008

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety findings and overall regulatory decision for phenothrin. While the full risk assessments and related supporting documents are not included in this document, they are available on the public docket at www.regulations.gov (docket # EPA-HQ-OPP-2008-0140) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for phenothrin for the purpose of making a reregistration eligibility decision. The Agency evaluated the toxicology, product and residue chemistry, and occupational and residential studies submitted for phenothrin and determined that the data are adequate to support a reregistration decision. A summary of the human health risk findings and conclusions are discussed below.

Food Quality Protection Act (FQPA) Findings

In the case of phenothrin, the toxicity database is incomplete for a full hazard evaluation, but is considered partially adequate to evaluate risk to infants and children. The uncertainties with respect to risks to infants and children are accounted for with the addition of the 10X FQPA uncertainty factor.

There is qualitative and quantitative evidence of increased susceptibility to infants and children from exposure to phenothrin. The studies assessing developmental neurotoxicity in rabbits indicated the presence of spina bifida at mid-dosage treatment levels, as well as the presence of hydrocephaly at the highest dose used. An unacceptable/non-guideline study in rats has also indicated the presence of piloerection (hair standing on end, resulting from stimulation of the nervous system) without axonal damage.

1. Toxicology

a. Toxicity Profile

Phenothrin is not known to be acutely toxic at high exposure levels to humans or mammals. Phenothrin exhibits low acute toxicity by oral (Category III), dermal (Category III), and inhalation (Category IV) routes of exposure. Phenothrin is mild eye irritant (Category III) but is not a skin irritant or a skin sensitizer.

The available toxicity data on phenothrin are adequate to assess phenothrin hazard potential. **Table 3** below presents the acute toxicity profile for phenothrin:

b. Toxicological Endpoints

Table 3. Acute Toxicity Profile – Phenothrin (Technical)

GLN No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral [Rat]	40908302	LD_{50} > 5000 mg/kg (no deaths)	IV
870.1200	Acute dermal [Rat]	40908303	LD_{50} >2000 mg/kg (no deaths)	III
870.1300	Acute inhalation [Rat]	43889301	LC_{50} > 2.1 mg/L (no deaths)	IV
870.2400	Acute eye irritation [Rabbit]	40908304	Mild irritant	III
870.2500	Acute dermal irritation [Rabbit]	40908304	Non-irritating	IV
870.2600	Skin sensitization [Guinea pig]	40908305	Not a sensitizer	

See **Table 4** for a summary of the toxicological endpoints used in the human health risk assessment for phenothrin.

The toxicity database for phenothrin is currently incomplete. The toxicity database lacks acute, chronic, and developmental neurotoxicity studies that are required to fully evaluate risks to infants and children. Due to the incompleteness of the toxicity database, the Agency has added the ten-fold (10X) database uncertainty factor (UF_{DB}) to the margin of exposure level (MOE) used to assess concerns for all exposures. The addition of this 10X database uncertainty factor

brings the total uncertainty factor for this assessment to 1,000 (including 10X to account for interspecies variation and 10X to account for intraspecies extrapolation).

i. Neurotoxicity

Phenothrin is known to achieve its insecticidal action through the disruption of neural activity. Phenothrin is a synthetic pyrethroid, and the pyrethroids alter the functions of both the peripheral and central nervous systems of mammals and insects.

Although phenothrin is lacking in acute, subchronic, and developmental neurotoxicity studies, neurotoxic effects were observed in the developmental toxicity studies that were submitted. Neurotoxic effects were not observed in other acute, chronic, and subchronic toxicity studies done in rats and dogs up to the limit dose of 20,000 mg/kg/day.

The Agency notes, however, that cats in particular may be especially sensitive to pyrethroid flea and tick treatments. In the year 2005, flea and tick spot-on products with phenothrin as the active ingredient were cancelled for use on cats and kittens due to incident reports and companion animal studies which indicated apparent neurotoxicity symptoms resulting from treatment, including excessive salivation, tremors, and/or seizures.

Based on the presence of neurodevelopmental effects in rabbits such as spina bifida, which began appearing at the lowest observed adverse effect level (LOAEL) of 100 mg/kg/day, the developmental no observed adverse effect level (NOAEL) was set at 30 mg/kg/day.

The phenothrin registrant, Sumitomo Chemical Company, Ltd., is currently in the process of conducting an acute neurotoxicity study for phenothrin. The Agency will review these data when they are submitted by the registrant.

ii. Developmental Toxicity

Maternal toxicity in rats was evidenced by the appearance of generalized clinical effects in dosed individuals; these effects included decreased maternal weight gain and decreased food consumption at the highest dosage tested of 3000 mg/kg/day. Thus, the maternal toxicity endpoints were determined to be 1000 mg/kg/day for the NOAEL and 3000 mg/kg/day for the LOAEL based on overall decreased weight of pups and developmental delays at the NOAEL dose of 3000 mg/kg/day.

iii. Reproductive Toxicity

The endpoints for reproductive toxicity were taken from a 2-generation reproduction study in rats in 1995. Parental animals that were exposed to phenothrin through regular feeding exhibited increases in spleen weight and decreased uterine weight. NOAELs and LOAELs were derived from the levels at which decreased weight gain, decreased food consumption, liver hypertrophy (liver enlargement), and microscopic changes in liver cells were observed in the parental animals. The systemic toxicity endpoints in the parental animals were set at 1,000 mg/kg/day and 3,000 mg/kg/day; these are the NOAEL and LOAEL dosages, respectively. The

toxicity endpoints for offspring were derived from the exposure level at which pup body weights decreased during the nursing period, with the NOAEL for offspring effects set at 59 mg/kg/day and the LOAEL set at 177 mg/kg/day.

iv. Dermal Toxicity

There are no studies of dermal absorption available specifically for phenothrin. Dermal absorption amounts were conservatively estimated to be 2.0% based on dermal absorption studies available for other pyrethroids and pyrethroid-like compounds. A previous study (2004) of the dermal absorption of pyrethrins in humans showed absorption at a 0.22% rate (MRID 46382501).[1]

A 21-day dermal toxicity study in rats (MRID 41009710) established a dermal NOAEL of 1000 mg/kg/day. A LOAEL was not established during this study since no effects were seen at the highest dose tested. Based on extrapolation from the developmental NOAEL of 30 mg/kg/day selected from the rat developmental study, and when accounting for the 2% absorption factor, the LOAEL for dermal exposure has been estimated to be 1,500 mg/kg/day. This LOAEL greatly exceeds the developmental limit dose (1,000 mg/kg/day) as well as the dermal toxicity NOAEL, which was determined to be 1,000 mg/kg/day. For this reason, neither developmental nor systemic effects resulting from dermal exposure are expected, and therefore a dermal endpoint was not selected.

vi. Inhalation Toxicity (Short- and Intermediate-Term)

The endpoints for the inhalation toxicity of phenothrin were taken from a subchronic inhalation study in rats that detected cellular changes in the nasal turbinates (the spongy bones of the nasal passages). The inhalation toxicity dosage for the NOAEL was set at 27 mg/kg/day, and the LOAEL was set at 75 mg/kg/day, which is the dosage at which the cellular changes in nasal turbinates were first observed.

Table 4. Summary of Toxicological Endpoints for Phenothrin		
Exposure Scenario	**Factor Used in Risk Assessment**	**Study and Endpoint of Risk Assessment**
Dietary Risk Assessment		
Acute Dietary (general population)	An acute RfD for the general population or any population subgroups was not selected; no effect attributable to a single (or few) day(s) oral exposure was observed in animal studies.	
Acute Dietary	Dose for risk assessment = 30	**MRID no: 41230003**

[1] **Studies Reviewed for Ethical Conduct (Internal Review Conducted by Agency Personnel)**

Selim, Sami. (2004) A single dose, open label study to investigate the absorption and excretion of orally administered or dermally applied [^{14}C]-labeled pyrethrin I (PI) to healthy male volunteers. Charles River Laboratories (CRL), Bayer AG, Pharma Bio-Research Clinics. SEL Study no SEL 0204, CRL Study no BTAZ-103, Pharma Bio-Research Code PBR-013911. 10/08/04. MRID 46382501 unpublished

Table 4. Summary of Toxicological Endpoints for Phenothrin		
(females 13-49)	mg/kg/day UF_A=10 UF_H = 10 UF_{FQPA}/UF_{DB} = 10 Acute RfD = 0.030 mg/kg/day	Developmental Toxicity Study – rabbit Developmental LOAEL = 100 mg/kg/day based on spina bifida
Chronic Dietary (all populations)	Dose for risk assessment = 7.1 mg/kg/day UF_A=10 UF_H = 10 UF_{FQPA}/UF_{DB} = 10 Chronic RfD = 0.007 mg/kg/day	**MRID no: 40276401** Chronic Toxicity study in dogs Chronic toxicity LOAEL = 26.8 mg/kg/day based on hepatocellular enlargement in the liver and focal degeneration in the adrenal cortex in both sexes.
Occupational/Residential Risk Assessment		
Incidental Oral Short-Term (1 - 30 days) and Intermediate-Term (1-6 months)	LOC for MOE = 1000 UF_A=10 UF_H = 10 UF_{FQPA}/UF_{DB} = 10	**MRID no: 40276404** 2-Generation Rat Reproduction Study NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on decreased body weight in parental animals and decreased weight gain during lactation of pups
Dermal Short/Intermediate- Term (1 - 30 days/1-6 months)	LOC for MOE = 1000 UF_A=10 UF_H = 10 UF_{FQPA}/UF_{DB} = 10	**MRID no: 41009710** Dermal toxicity systemic 21-day dermal toxicity study in rats LOAEL = not established 21/28 Dermal toxicity study in rats dermal toxicity systemic LOAEL not established up to 1000 mg/kg/d (HDT)
Inhalation Short-, Intermediate-Term (1 - 30 days, 1-6 months)	Residential LOC for MOE = 1000 Occupational LOC for MOE = 1000 UF_A=10 UF_H = 10 UF_{FQPA}/UF_{DB} = 10	**MRID no: 41289201** Subchronic inhalation study in Sprague-Dawley rats NOAEL = 26.6 mg/kg/day LOAEL = 74.7 mg/kg/day based on histopathological changes in the cells of nasal passages.
Cancer (oral, dermal, inhalation)	**MRID no: 40276402** Classification: Not likely to be carcinogenic to humans	

UF = uncertainty factor, UF_A = uncertainty factor for intraspecies extrapolation, UF_H = uncertainty factor for interspecies (human) extrapolation, UF_{FQPA}/UF_{DB} = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

2. The Carcinogenicity of Phenothrin

The Agency has made the finding that phenothrin is "not likely to be carcinogenic to humans." This classification was based on studies showing that the hepatocellular carcinomas and hepatocellular adenomas (tumors and benign growths occurring on the liver) which occurred appeared only at the excessively toxic limit dose of 20,000 ppm in rat studies. The appearance of these adenomas and carcinomas did not achieve statistical significance and therefore the Agency concluded that phenothrin is not likely to be carcinogenic. Acceptable mutagenicity studies were also submitted for phenothrin, but no mutagenic potential for phenothrin was indicated.

3. Dietary Exposure and Risk from Food and Drinking Water

Dietary assessments are conducted by calculating a reference dose (RfD) for each pertinent population from the appropriate toxicity study. The reference dose is adjusted to account for the appropriate safety factors resulting in a Population Adjusted Dose (PAD). A risk estimate that is less than 100% of the acute PAD (aPAD) or chronic (cPAD) does not exceed the Agency's risk concerns.

The acute and chronic dietary and drinking water risks were assessed to include the proposed new food use with the 0.01 ppm tolerance on crops that was requested by MGK Company.

a. Acute Dietary Risks (Food and Drinking Water)

EPA conducted a conservative Tier 1 acute dietary and drinking water exposure assessment for the proposed new food use of phenothrin. The acute dietary exposure assessment assumed residues at tolerance levels on plant and animal commodities, 100% of crops treated, and default processing factors. The assessment was conducted for all commodities and incorporated the estimated surface water peak concentration of phenothrin of 0.1 ppb (parts per billion).

The acute reference dose (or aRfD) was calculated based on the developmental toxicity endpoint because developmental affects are the only effects which might result from acute exposure, and thus only females 13-49 would be at risk from any possible developmental toxicity. An aPAD was not calculated for the general population or other subpopulations because no adverse effects were observed from a single day or a few days of phenothrin oral exposure.

The acute dietary exposure assessment has determined that acute dietary exposures for females 13-49 years are below EPA's level of concern. The DEEM exposure estimate for this subgroup is 1.3% of the aPAD.

b. Chronic Dietary Risks (Food and Drinking Water)

EPA conducted a conservative Tier 1 chronic dietary assessment and drinking water assessment. Like the acute dietary assessment, the chronic dietary exposure assessment assumed residues at tolerance levels on plant and animal commodities, 100% of crops treated, and default processing factors.

Concentrations in surface and drinking water were estimated to be 0.04 ppb for chronic exposures. The chronic dietary assessments have determined that risks for the general U.S. population and all other population subgroups fall below the Agency's level of concern. Children 1-2 years old constituted the most highly exposed population subgroup; their dietary exposure estimate is 13% of chronic PAD (cPAD).

4. Residential Exposure and Risk

Residential risks are further detailed in the *Revised Occupational and Residential Exposure Assessment.*

a. Residential Exposure Data and Assumptions

The assumptions used to assess the post-application exposure from foggers and aerosol sprays in the indoor residential settings (typical of the kind used to dispense phenothrin) were based on data provided by the Non-Dietary Exposure Task Force (NDETF).

In addition to the use of indoor sprays, foggers, powders, and outdoor lawn and garden sprays, ultra low volume (ULV) sprayers used for mosquito abatement can contribute to the possible residential exposure from phenothrin. ULV sprayers dispense aerosols in fine droplets which are designed to stay aloft for long periods of time and kill flying mosquitoes on contact. Because of the fine droplet size used, the concentration of an aerosol dispensed with ULV sprayers is very low in relation to the amount of area treated and can be less than 3 ounces of formulated product per acre.

Residential exposure from ULV sprayers occurs when sprayers are used in residential areas as a part of municipal mosquito control operations. For purposes of the residential risk assessment, it was assumed that full application rates from a truck-mounted ULV sprayer were available in the breathing zone of a residential bystander. (The breathing zone encompasses the cubic volume of airspace that could be inhaled by a bystander; a 1% dilution factor was also assumed. A dilution factor of 1% assumes that 1% of the product that is released is available for inhalation).

b. Chemical-Specific Exposure Assumptions

Phenothrin shares close structural similarities with the pyrethrins and permethrin, and also shares similar use patterns with these chemicals. Because of these similarities, the Agency believes that the NDETF data for the pyrethrins and permethrin provide appropriate surrogate data for phenothrin exposure. Permethrin and phenothrin are both synthetic pyrethroids, and so

permethrin data were used preferentially as surrogates. The NDETF's scenario-specific data for the pyrethrins and permethrin were used to determine the deposition of phenothrin on vinyl flooring and carpeting following the use a of total release indoor fogger.

c. Residential Handler and Post-Application Exposures

Residential exposure estimates are expressed in terms of Margins of Exposure (MOE). In numerical terms, the MOE is the NOAEL divided by a numerical measure of the expected amount of exposure. A target level of concern (LOC) or MOE of 1000 is considered safe for inhalation, incidental oral, and residential exposures and risks. Deterministic modeling estimated that several residential exposure scenarios would result in exposures of concern (MOE ≤ 1000): the incidental ingestion of residues on pets via hand-to-mouth after pet spot-on or spray treatment by toddlers (children 1-2 years of age) and the incidental ingestion of residues on carpets or vinyl flooring by toddlers after fogger or carpet powder treatment (without vacuuming). The results of the deterministic assessments for residential use products are detailed in **Table 5** below. Assessments were further refined for the MOEs which are bolded.

Table 5. Deterministic Residential Exposure and Risk Estimates

Use	Exposure Scenario	MOE
Residential Applicator, Inhalation Exposure		
Contact Spray/Crack & Crevice	RTU Aerosol Spray	26000
Outdoor House and Garden	RTU Aerosol Spray	390000
Mosquito Adulticide Application, Inhalation Exposure		
Adult	Aerial Spray from Aircraft	>1000000
Child	Aerial Spray from Aircraft	>1000000
Adult	Truck-Mounted ULV Sprayer	422000
Child	Truck-Mounted ULV Sprayer	113000
Toddlers Reentering Treated Lawns, Incidental Ingestion		
Hand to Mouth	Space Spray	34000
Object to Mouth	Space Spray	136000
Incidental Soil Ingestion	Space Spray	>1000000
Toddlers Reentering Treated Flooring, Incidental Ingestion		
Playing on Carpet	Fogger Formulation	**200**
Playing on Vinyl Flooring	Fogger Formulation	**780**
Playing on Carpet (No Vacuum)	Carpet Powder	**415**
Toddlers Playing with Pets, Incidental Ingestion		
Post-Application	Aerosol Spray	**950**
Post-Application	Spot On	**46**
During and After Indoor Application, Inhalation Exposure		
Adult (Application and Re-Entry)	Aerosol Space Spray	11800
Child	Aerosol Space Spray	3300

4.2 Probabilistic Post-Application Residential Exposure and Risk Assessment

The Agency has typically used deterministic methods (otherwise known as point estimates) to determine exposure amounts. The Agency has begun to explore probabilistic approaches to estimate exposure amounts in the past few years, and such approaches are considered to be refinements over deterministic assessments. Probabilistic assessments provide more information regarding the possible variety of exposure routes and the probability of receiving a range of doses during an exposure event. Probabilistic approaches provide a distribution of exposure assessments, rather than a single, (perhaps high-end), point estimate of exposure.

4.2.1 The CARES Probabilistic Assessment for Post-Application Residential Risks

The Agency used the CARES (Cumulative and Aggregate Risk Evaluation System) modeling tool to assess residential post-application risks. CARES is a publicly available software program (CARES® Version 3.0; http://cares.ilsi.org). The CARES assessment focused on those MOEs of concern first identified by the deterministic residential assessment. These scenarios included post-application incidental oral exposure from pet care products, and exposure from indoor foggers and carpet powders.

The CARES model uses a reference population of 100,000 individuals selected from the 1990 U.S. Census. The reference population is then divided into subgroups; these subgroups are categorized by race and age. (Children ages 1-3 are a subgroup, for example). Using these reference populations, CARES simulates 24-hour exposures over the course of 365 days for each person in a specified subpopulation based on the routes of exposure, empirical data about a subpopulation's behavior, and exposure algorithms.

The probabilistic CARES assessment for phenothrin assumes that post-application exposure begins on the "day of application." Five thousand (5000) product uses are assessed for each exposure scenario, i.e., percentile distributions for each exposure scenario are generated from 5,000 different exposure estimates.

4.2.2 CARES Exposure Routes and Scenarios

The probabilistic CARES assessment was conducted only for those post-application exposure scenarios identified in the deterministic assessment which presented risks of concern (MOE $\leq$ 1000). Maximum application rates used to assess these scenarios were determined by a review of active labels and/or information provided by the registrants, and were used for all types and methods of application. The following scenarios were assessed probabilistically using standard EPA algorithms for exposure estimation and with distributional inputs.

1) Toddler incidental ingestion of residues deposited on carpet and vinyl flooring via hand-to-mouth activities after use of total release foggers.

2) Toddler incidental ingestion of residues on pets via hand-to-mouth after pet spot-on treatment.

3) Toddler incidental ingestion of residues deposited on carpet via hand-to-mouth activities after use of carpet powder.

The results of the CARES assessment for residential use products are detailed in **Table 6** below.

4.2.3 Probabilistic Exposure and Risk Estimates

The results of the probabilistic CARES assessment for the post-application incidental oral exposure scenarios outlined in Section 3.2.2 are presented in **Table 6**. Risks are presented in the form of MOEs by percentile of exposure.

Label requirements for the carpet powder direct the user to keep children and pets out of the treated room for 2 hours after application and then vacuum. The CARES assessment model assumes that a vacuum with at least 30% removal efficiency is used. When use of a vacuum with removal efficiency of 30% is assumed, MOEs greater than 1000 were seen at the 99.9th percentile.

Table 6. CARES Assessment – Phenothrin MOEs for Children 1-2 years, Incidental Oral Exposure – LOC/MOE = 1000

Percentile	Exposure Scenario and Route			
	Pet Care Spray	**Pet Care Spot-On**	**Indoor Carpet Powder Vacuum 30% Efficiency**	**Indoor Fogger**
99.9	2489	**674**	1170	5027
99.5	3592	**860**	1492	6527
99	3924	1017	1674	8427

5. Benchmark Dose Assessment

Since the incidental oral exposure from the CARES assessment using a NOAEL resulted in assessed risks above the Agency's LOC, the Agency used a benchmark dose analysis to further refine the assessment of risks to toddlers from exposure to pet spot on products.

There are adequate data on which to base a benchmark dose for phenothrin and the Agency conducted an analysis using the effect of organ weight gain to set the appropriate BMDL of 100 mg/kg/day.

The benchmark dose used and the MOE values calculated from the CARES assessment for toddler hand to mouth exposures are presented in Tables **7** and **8** below.

Table 7. Exposure Scenario and Point of Departure for the Benchmark Dose Assessment			
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**Study and Toxicological Effects**
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1-6 months)	$BMDL_{10}$ = 100 mg/kg/day	UF_A= 10 x UF_H= 10 x UF_{DB} /UF_{FQPA}= 10x	2-generation rat reproduction study. The NOAEL is 1000 ppm (50 mg/kg/day). The LOAEL is 3000 ppm (150 mg/kg/day) based on decreased body weight (4-6%) and increased liver weight in F0 and F1 parental animals, and an increase in absolute and relative spleen weight, and decreased absolute uterine weight in F1 adults and on decreased body weight gain during lactation of F2b pups, and decreased litter size of F1b litters at day 1, decreased absolute heart and kidney weight in F2b males, increased relative liver weight in male and female F2b pups.

BMD_{10} = The dose associated with a 10% change of a biological effect. $BMDL_{10}$ = A lower one-sided confidence limit on the BMD_{10} UF = uncertainty factor, UF_A = uncertainty factor for intraspecies extrapolation, UF_H = uncertainty factor for interspecies (human) extrapolation, UF_{FQPA}/UF_{DB} = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Table 8. Incidental Oral MOEs for Pet Care Spot-On Target MOE = 1000	
Percentile	**Estimated LOC/MOE**
99.9	1350
99.5	1700
99	2000

6. Aggregate Exposure and Risk

Aggregate risk assessments consider the possibility that certain members of a population will be exposed to a pesticide through multiple routes and that the effects of these multiple exposures will be additive. With the addition of a food use tolerance, phenothrin exposure can occur through the food, water, and residential pathways. Generally, the estimated average exposure from food and drinking water is added to the risks from incidental oral and inhalation exposure to arrive at an estimate for the short-term aggregate risk from all possible exposure pathways. For phenothrin, however, the risks were not aggregated because the dietary, incidental oral, dermal, and inhalation endpoints are all based on differing effects. Therefore, an aggregate risk assessment is not possible for phenothrin.

7. Occupational Exposure and Risk

Twelve occupational exposure scenarios were assessed for the reregistration eligibility decision. Only short- and intermediate-term duration inhalation exposures are expected to occur during occupational use scenarios based on expected usage and toxicity patterns. Occupational post-application exposure scenarios were not assessed; based on use pattern descriptions, post-application exposure from worker re-entries into treated areas is not expected. Phenothrin is applied as a ULV spray; ULV applications typically involve very low amounts of product applied over a relatively large area. Post-application exposures are also not expected to occur in

other settings because phenothrin does not produce dermal toxicity and is not volatile, and so it will not produce inhalation exposure risks following ULV applications.

a. Occupational Handler Exposure and Risk

The term "handler" refers to those who mix, load, and apply a pesticide product. All occupational handler scenarios must reach or exceed an MOE of 1000 in order to pass the Agency's LOC. Deterministic risk estimates for the occupational handlers indicated only one occupational exposure of concern (MOE < 1000) for the occupational handler scenario of mixing, loading, and applying liquids with a high pressure wand in a non-food greenhouse at the maximum use rate.

The MOE for this occupational use scenario is 194 if no protective equipment is assumed. With the addition of PF5 respirator, the MOE for this use scenario is calculated to be 970. While 970 is still below the target MOE of 1,000, the Agency does not consider this application scenario to present risks of concern, given underlying, conservative assumptions in the risk assessment, including the assumption that 1,000 gal/day (the maximum allowed area treated) is applied at the maximum allowable rate.

All other occupational exposure scenarios do not result in risks of concern (MOEs ≥ 1000). Estimates of potential occupational exposures of concern are detailed in **Table 9**.

Table 9. Estimated Phenothrin Exposure & MOEs for Greenhouse Non-food Mixer/Loader/Applicator –Short and Intermediate Term LOC/MOE < 1000

Exp Scenario [1]	Inhalation Unit Exposure (µg/lb ai)	Application Rate [3] (APR)	Daily Area Treated [4]	Inhalation Dose (mg/kg/day) [5]	Inhalation MOE [6]
High Pressure Hand wand **Maximum APR**	120	0.08 lb/ai gal	1000 g/day	0.1251	**194**
High Pressure Hand wand **Maximum APR PF5 Respirator**	24	0.08 lb/ai gal	1000 g/day	0.0137	**970**
High Pressure Hand wand **Typical APR**	120	0.008 lb/ai gal	1000 g/day	0.0137	1940
Max AR = 0.01 x 8.35 lb ai/gal = 0.08 lb ai/gal (1% ai); Typical AR = 0.001 x8.35 lb ai/gal = 0.08 lb ai/gal (0.1%)					

[1] Baseline PPE inhalation unit exposures represent no respirator. Values are reported in the PHED Surrogate Exposure Guide dated August 1998 or are from data submitted by the Outdoor Residential Exposure Task Force dated May 2000.

[2] Application rates are based on maximum values based on label review and/or information provided by registrants.

[3] Amount treated is based on the area or gallons that can be reasonably applied in a single day for each exposure scenario of concern based on the application method and formulation/packaging type. (Standard EPA/OPP/HED values). 5 gal per day application rate for backpack spray mosquito application based on label specified application rate of 2 mph.

[4] Inhalation dose (mg/kg/day) = [unit exposure (ug/lb ai) * 0.001 mg/ g unit conversion * Inhalation absorption (100%) * Application rate (lb ai/acre or lb ai/gallon) * Daily area treated/amount handled (acres or gallons)] / Body weight (70 kg).

[5] Inhalation MOE = short-term and intermediate-term endpoint for inhalation; (inhalation NOAEL 26.6 mkd)/ Daily Inhalation Dose.

8. Incident Report Data

The following data bases were consulted for poisoning incident data on the active ingredient phenothrin: OPP Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Institute of Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risks (SENSOR).

The IDS review showed 39 incidents reported since 1992. Reports submitted to the IDS typically represent anecdotal reports or allegations only; therefore no conclusions can be drawn implicating the pesticide as a cause of any of the reported health affects unless supported by results from other data sources or the individual incidents are well documented.

A total of 2342 occupational and non-occupational exposure cases were reported to PCC for the period from 1993-2005; 309 of these cases resulted in a visit to a health care facility. No trend in total exposure, symptomatic cases, or cases that resulted in a visit to a health care facility is apparent for the 13 year-span of data collected on phenothrin. The data indicate a steady average of about 180 exposures per year, 46 symptomatic cases per year, and 23 cases per year resulting in a visit to a health care facility. The health symptoms observed in PCC reported exposure cases included gastro intestinal effects (nausea, throat irritation, and vomiting), dermal effects (skin irritation/pain, pruritis, rash, and erythema) neurological effects (headache, and dizziness/vertigo) and ocular effects (eye irritation).

Detailed descriptions of 44 cases submitted to the CDPR California Pesticide Illness Surveillance Program (1998-2004) were reviewed. In five of these cases, phenothrin was used alone or was judged to be responsible for the health effects.

Based on the NIOSH SENSOR data for 1998 to 2003, there were four occupationally related cases involving phenothrin. Three cases were reported in Washington State and one in Florida. All reported cases produced mild symptoms including, allergic rhinitis exacerbation, asthmatic response to insecticide, and pruritis.

8.1 Companion Animal Incidents

Flea and tick uses for phenothrin products on cats and kittens have been cancelled since the year 2005. These products were cancelled in response to the number of incident reports the Agency received detailing cases of serious illness or deaths among cats and kittens resulting from the use of phenothrin flea and tick products. In addition to the companion animal incidents reported for cats and kittens prior to 2005, the Agency has received, over the past ten years, a handful of reported incidents of the appearance of apparent neurological symptoms and other various complications following phenothrin flea and tick treatment on dogs.

B. Environmental Risk Assessment

For a complete discussion of ecological risks, see the *Environmental Fate and Effects Science Chapter for the Reregistration Eligibility Decision of Phenothrin*.

The screening-level risk assessments conducted by the Agency rely on a method of determining risk known as the risk quotient (RQ). RQs are calculated by dividing measures of exposure by measures of a pesticide's toxicity. This commonly used measure of exposure equals the estimated environmental concentration (EEC) of a particular pesticide, divided by a common measure of a pesticide's toxicity, such as the no observed adverse affect concentration (NOAEC) or the LD_{50}. (The LD_{50} is the dosage which will kill 50 percent of test organisms during a set time period.) Risk quotients are then compared to levels of concern (LOCs), which indicate potential risks to non-target organisms and the possible need for regulatory action.

It should be noted that the potential ecological risks described in the *Environmental Fate and Effects Assessment* result from the widespread broadcast applications of phenothrin using ULV sprays. The ULV spray use pattern is the only use pattern which is expected to result potential ecological risks of concern; the majority of phenothrin products formulated for residential or occupational use are intended for use indoors. Therefore, although these products exhibit high amounts of toxicity to non-target terrestrial and aquatic organisms, few opportunities for ecological exposures are expected.

1. Environmental Fate and Transport

Phenothrin appears to be moderately persistent under aerobic conditions. The major routes of dissipation of phenothrin into the environment appear to be aqueous photolysis (photolysis in water) at 6.5 days and aerobic metabolism (in the soil from 18.6-25.8 days, and in aquatic environments at 36.1 days). Phenothrin also appears to be persistent under anaerobic conditions, with an anaerobic metabolism of 173.3 days. It is stable to hydrolysis at all pH levels.

Phenothrin's moderate persistence in surface soils, its relatively high affinity for binding to soils, and low solubility indicate a high potential for the chemical to enter surface waters during runoff events that contribute to soil erosion during the weeks following an application event. Phenothrin could also reach surface waters as the result of spray drift following an application with ULV equipment. Its low leaching potential, however, also means that it is likely to remain immobile once it binds to soil sediments. Furthermore, it is unlikely to seep into groundwater supplies and cause contamination. Even though phenothrin is likely to undergo photolysis in water, its high affinity for binding to particulate matter make photolysis less likely to happen, except during the brief period in which the chemical is suspended in water without binding to sediment. The photolysis of phenothrin is expected to occur in shallow waters or in the upper levels of the water column where sunlight is able to penetrate. Phenothrin's large binding affinity for sediment or suspended solids in the water column also indicate a high potential for continued persistence in aquatic systems.

The aquatic metabolism studies conducted with phenothrin have shown that phenothrin partitions quickly into sediment. This is further supported by its high K_{oc} coefficient, (K_{oc} =

141,000); the leaching potential of phenothrin is very low. Leaching does not appear to be a significant route of dissipation for phenothrin. Volatilization of the chemical is unlikely because of phenothrin's low vapor pressure and Henry's Law Constant.

A supplemental aqueous photolysis study has suggested that aqueous photolysis may be a route of dissipation for phenothrin. It is possible that phenothrin photolyzes like resmethrin because of the structural similarity between the two chemicals.

The inputs used for the supplemental aqueous photolysis study could affect the results of the long-term EECs (21 day and 60 day average) and thus the RQs calculated from these EEC values. Modeling was based on a K_{oc} derived from a non-guideline study; this K_{oc} was also an input parameter into PRZM/EXAMs modeling construct used to estimate aqueous concentrations of pesticides. The K_{oc} obtained from this study was very high, in line with other K_{ocs} obtained for other synthetic pyrethroids, and so additional studies were not required.

Only the parent chemical phenothrin was considered in the food and drinking water assessments because its degradates are essentially non-toxic. Data gaps exist for the degradates concerning their pattern of decay, their mobility, and their potential for offsite transport. Due to the phenothrin's degradates low toxicity, however, these data are not being required. In summary, it is not expected that any phenothrin degradate will produce significant toxic effects on aquatic life, wildlife, or plants.

Continual or repeated applications could allow sediment areas to become repositories of phenothrin adsorbed to solids, as the chemical is subject to very slow biodegradation. Organisms living in benthic environments may be impacted by this potential accumulation.

Based on phenothrin's octanol/water partition coefficient of 1×10^6, it could have the potential to bioaccumulate in fish. The maximum bioconcentration factors in bluegill sunfish were 4,000, 645, and 1,805 for non-edible, edible, and whole fish tissues. However, bioaccumulation was limited by the depuration (the removal of concentrations of a pesticide compound from the body of an organism) of phenothrin. Over 88.2% of phenothrin residues in fish body tissues dissipated after 14 days, and the depuration half-life of phenothrin is 2.4-3.7 days.

2. Ecological Exposure and Risk

Phenothrin has the potential to impact the functioning of ecological systems due to its widespread use as a mosquito adulticide employing application with ULV sprayers. Various freshwater, estuarine/marine, and terrestrial ecosystems are potentially at risk from phenothrin spray drift and runoff following a ULV application. Phenothrin's use across the southern and southwestern United States further increases the potential that non-target ecosystems will be placed at risk for exposure.

Phenothrin has a high affinity for binding to organic carbon and particulate matter. Unbound phenothrin is unlikely to remain free in the water column for any significant period of time. If multiple applications are made, however, phenothrin bound to sediment and free in the

water column could accumulate significantly in aquatic ecosystems. Acute and chronic exposure risks from phenothrin exist to organisms living in the water column and in the benthic sediments lining water bodies.

a. Aquatic Organisms

Aquatic Exposure Modeling

Phenothrin and other pesticides which are used in municipal mosquito control operations require special modeling considerations because of their dispersal with ULV sprayers. To estimate aquatic exposures, spray drift was calculated using the AGricultural DISPersal model (AGDISP v. 8.15.0.4 10/31/06), commonly called the AGDISP computer model. AGDISP provides estimates of application efficiency on treated areas and on the downwind deposition of spray material released from an aircraft. Using the most conservative scenario of a 1-day interval, the peak EECs in the water column ranged from 0.080 ppb to 0.325 ppb. Modeled pore water EECs were approximately 16-23% of the peak surface water EECs.

Acute and Chronic Toxicity to Aquatic Organisms

Toxicity studies for both the phenothrin technical grade active ingredient (TGAI) and formulations were used for the risk assessment for aquatic organisms when they were available. Phenothrin TGAI is very highly toxic on an acute basis to freshwater and estuarine/marine fish and invertebrates. Chronic data for phenothrin show adverse reproductive effects for freshwater invertebrates at a NOAEC of 0.47 µg a.i/L. This indicates a potential for chronic reproductive effects to freshwater invertebrates as a result of phenothrin exposure. Additional chronic effects to estuarine and marine invertebrates are expected based on the chronic reproductive toxicity to freshwater invertebrates and the acute effects to estuarine and marine invertebrates.

Based on the additional evidence present in the pyrethroid database, aquatic organisms exposed to phenothrin could be subject to abnormal reproductive, growth, and developmental effects.

Table 10 summarizes the specific measurement of endpoint values selected to evaluate the risks of phenothrin to aquatic organisms.

Risk to Aquatic Organisms

(1) Freshwater and Estuarine/Marine Fish

Phenothrin is highly toxic on an acute basis to freshwater fish, with median lethal concentrations, or LC_{50}s, ranging from 15.8 to 18.3 µg a.i/L. Phenothrin is also highly toxic to estuarine/marine fish on an acute basis. LC_{50}s for estuarine and marine fish range from 38.3 to 94.2 µg a.i/L. The NOEC for chronic freshwater fish is 1.1 based on supplemental data.

RQs below 0.1 are considered below the Agency's LOC for acute risks to listed aquatic organisms. RQs for acute freshwater fish exposure were calculated from supplemental data and

EECs from AGDISP, and were determined to be $\leq$ 0.05. These RQs indicate no effect based on the level of exposure. The RQs calculated using supplemental data from the acute estuarine/marine fish study were < 0.01, and also indicate no effect based on estimated exposure levels.

RQs below 1.0 are considered below the Agency's LOC for chronic risks to aquatic organisms. Based on the results of the AGDISP model for phenothrin, an EEC of 0.196 ppb was estimated on PA turf, assuming 26 applications were applied with a 1-day application interval at a rate of 0.0036 lb. a.i./A. From this estimated EEC, the RQ for chronic risk to freshwater fish was calculated to be 0.2; this RQ is below the Agency's LOC for chronic risks to aquatic organisms. No toxicity was available to calculate the chronic RQ for estuarine/marine fish.

(2) Freshwater and Estuarine/Marine Invertebrates

Phenothrin is very highly toxic to freshwater invertebrates. The EC_{50} for freshwater invertebrates is 4.4 µg/L. Based on this toxicity value, the RQs for acute risks to freshwater invertebrates were $\leq$ 0.07. These RQs are below the Agency's LOC for non-listed species, but are above the Agency's LOC of 0.05 for aquatic endangered species. The chronic toxicity reproduction endpoint for Daphnia is a NOAEC of 0.47 µg/L. The RQs for chronic risks to freshwater invertebrates range between 0.11-0.55 and are below the Agency's LOC for chronic risks to freshwater organisms.

The estuarine invertebrates tested are more sensitive to phenothrin than freshwater invertebrates with a EC_{50} of 0.025 µg/L. The RQs for acute risks to estuarine/marine invertebrates were calculated to range from 3.20 to 13.00, which indicates acute risks to estuarine/marine invertebrates based on exceedance of the Agency's LOC. Chronic toxicity for estuarine invertebrates is based on acute to chronic ratio from freshwater organisms and RQs range between 19.61-99.61, which also indicates chronic risks to estuarine/marine invertebrates based on LOC exceedance.

(3) Freshwater and Estuarine/Marine Benthic Organisms

Although there are no acute or chronic sediment toxicity studies for benthic organisms, the risks of phenothrin exposure to benthic organisms are assumed to be similar to that of other aquatic invertebrates. Data from aquatic invertebrate organisms (e.g. *Daphnia* and pink shrimp LC_{50}s and EC_{50}s) phenothrin TGAI exposures were used as surrogate toxicity data for aquatic invertebrates.

RQs for acute risks to freshwater benthic organisms are $\leq$ 0.02, indicating that acute risks to freshwater benthic organisms are below the Agency's LOC. RQs for chronic risks to freshwater benthic organisms are < 0.16, which also fall below the Agency's LOC for aquatic organisms.

(4) Aquatic Plants

There are no acceptable data available evaluating the toxicity of phenothrin TGAI to algae or aquatic macrophytes. Therefore, risks to aquatic plants from phenothrin exposure cannot be assessed, and remains an uncertainty.

There are no incident reports which describe the toxicity of phenothrin or other synthetic pyrethroids to aquatic plants. Phenothrin, along with the other pyrethroid insecticides, acts as a neural toxin, so it is highly unlikely that phenothrin will produce phytotoxic effects. Since (1) several pyrethroids have agricultural or ornamental uses and can be applied to plants without adverse effects to plants, and (2) phenothrin is applied at very low application rate, there is low likelihood for risk to plants. Because label instructions indicate that phenothrin is not to be sprayed over or around water bodies, direct effects from application to aquatic plants are not expected.

Table 10. Toxicity Values for Aquatic Organisms Exposed to Phenothrin Technical Grade Active Ingredient (TGAI)

Exposure Scenario	Exposure Duration	Toxicity Value (µg/L)	Endpoint	MRID
Freshwater Fish				
Acute Rainbow Trout	96-hours	16.7	Mortality	40908308 Supplemental
Bluegill Sunfish	96-hours	15.8	Mortality	40908308 Supplemental
Chronic Rainbow Trout	60-day post-hatch survival	NOEC 1.1	Reproduction	44587002 Supplemental
Freshwater Invertebrates				
Acute Water flea TGAI (*Daphnia magna*) (93.4%)	48 hours	LC_{50} = 4.4	Mortality	44407901 Acceptable
Chronic Water flea *(Daphnia magna)* (93.4%)	21-day	NOAEC = 0.47	Reproduction	44587003 Acceptable
Acute Freshwater Benthic Organisms	No data currently available. Risk to benthic organisms is assumed to be similar to that of organisms living in the water column. Data from water column invertebrates is used to assess risk to benthic organisms in the absence of toxicity data			
Estuarine/Marine Fish				
Inland Silverside TGAI (93.4%)	96-hours	LC_{50} > 38.3 LC_{50} = 94.23	Mortality	44388901 Supplemental 44388902 Supplemental

Estuarine/Marine Invertebrates				
Mysid TGAI (93.4%)	96-hours	LC_{50} = 0.025	Mortality	44388903 Acceptable
Estuarine/Marine Benthic Organisms				
Acute	No data currently available**.** In the absence of toxicity data that characterizes the effects of phenothrin exposure to benthic organisms, the most sensitive measures of effect for estuarine/marine invertebrates (i.e. mysid LC_{50}'s) were used as surrogate toxicity data for this taxonomic group.			
Chronic	No data currently available for benthic organisms. No chronic estuarine/marine toxicity data are available.			

b. Terrestrial Organisms

(1) Terrestrial Mammals

Exposure to phenothrin in terrestrial non-target mammals is not expected to result in acute or chronic risks (to either listed or non-listed species). Previous studies with rats have shown that phenothrin is non-toxic to mammals in acute doses, based on an $LD_{50} \geq 5{,}000$ mg a.i. /kg/bw (body weight). Because of this high LD_{50} dose, risk for non-target terrestrial mammals is expected to be low to non-existent. This high LD_{50} of 5,000 mg a.i./kg/bw greatly exceeds any concentration of phenothrin that terrestrial mammals are likely to encounter in the environmental, resulting in an RQ value for terrestrial mammals that is equivalent to zero. Thus, no acute risks to terrestrial mammals are expected.

Although the chronic reproductive toxicity studies described in the human health toxicity section of this document describe adverse growth and reproductive effects, such as decreased female weight gain, decreased body weight in both sexes, and decreased pup weight, this assessment of toxicity found that all risk quotients from these chronic toxicity exposures are below the Agency's LOC.

In the chronic reproductive toxicity studies performed in rats, the LOAEL for (maternal) toxicity was determined to 3,000 ppm. As with the acute assessment for terrestrial mammals, this value of 3,000 ppm results in a chronic RQ that is equivalent to zero. Chronic risks to terrestrial mammals are not expected.

(2) Avian Toxicity

Based on studies of avian acute dietary toxicity, phenothrin can be classified as practically non-toxic to avian species. The level of concern for avian dietary toxicity is above 5,000 ppm a.i. ($LC_{50} > 5{,}000$ ppm a.i.). Acute dietary exposure is not expected to be a risk for avian species, even at maximum application rates.

Avian acute oral toxicity tests have also indicated that phenothrin is practically non-toxic to avian species. With the $LC_{50} > 5{,}000$ ppm a.i., avian risks are expected to be low. Acute oral exposure is not expected to be a concern for avian species, even at maximum application rates.

As with the acute toxicity risks to terrestrial mammals, the high LC_{50} > 5,000 ppm a.i. greatly exceeds any expected environmental concentration that avian species are likely to encounter, resulting in an RQ for acute avian toxicity that is equivalent to zero. Based on this RQ, acute risks to avian species are not of concern.

The Agency has no data to assess chronic risks to birds from phenothrin use. However, data for other pyrethroids show potential chronic effects at high doses, but no risks from current use patterns. Based on this information, plus the lack of chronic risks for mammalian species and the low rates of application for phenothrin, the Agency concludes that there is low likelihood of chronic risks to birds from phenothrin use.

(3) Non-Target Terrestrial Insects

Phenothrin has been demonstrated to be highly toxic on an acute contact basis to non-target terrestrial insects, particularly to honeybees. Honeybees may also face indirect dietary risks from phenothrin toxicity. In addition to phenothrin's high toxicity, the potential for non-target insect exposure to phenothrin is high because phenothrin is most often applied between April to October to control mosquitoes; non-target insects are also at their most active during this time of year. Because of the large exposure potential and high toxicity determination, phenothrin may pose significant acute risks to non-target insects.

(4) Terrestrial Plants

There are no data available evaluating the risks of phenothrin exposure to non-target terrestrial plants, so the amount of risk to terrestrial non-target plants cannot be assessed and remains an uncertainty. No incident reports have connected phytotoxic incidents associated with the application of phenothrin or any other synthetic pyrethroid to phytotoxic effects, despite its application on or near agricultural plants. Phenothrin, along with the other pyrethroid insecticides, acts as a neurotoxicant, so phytoxicity from phenothrin use is not expected.

c. Risk Characterization

The Agency does not believe that ecological exposures and risks will result from the residential and occupational uses of phenothrin products. The mosquito adulticide use is the predominant widespread outdoor use, and phenothrin is applied at very low application rates. Most other phenothrin products are spot treatments and have very low application rates. Many of the residential products that would eventually reach wastewater systems have very low percentages of phenothrin active ingredient (e.g. pet shampoos). The rapid degradation of the phenothrin parent molecule in surface waters also greatly decreases the likelihood of ecological exposures via wastewater which feeds into surface water bodies.

The phenothrin database is lacking a study on photodegradation on soil, acceptable studies that examine chronic toxicity exposures to fish, and toxicity to algae or aquatic macrophytes. A confirmatory study on photodegradation on soil study is required at this time to complete the assessment of phenothrin's ecological risks.

3. Ecological Incidents

There are no ecological incidents involving aquatic or terrestrial phenothrin exposure reported to EPA or tracked by EIIS (the Ecological Incident Information System).

4. Threatened and Endangered Species Concerns

Screening-level risk assessments for endangered species broadly considers each listed species as represented by a member of each taxonomic group at risk. Endangered species are conservatively assessed in this manner, which assumes that all members of a taxonomic group will be located in the area treated with a particular pesticide. Terrestrial organisms and aquatic organisms are assumed to reside either in or adjacent to treated sites. Listed species are also assumed to receive the maximum possible pesticide exposure within a treated area.

There are no direct risks of concern for listed freshwater benthic organisms, fish, birds, or mammals for any exposure pathway based on LOC exceedance. There are potential concerns for listed aquatic invertebrates based on this screening-level assessment.

For a full discussion of endangered species RQ determinations, please see the *Environmental Fate and Effects Science Chapter for the Reregistration Eligibility Decision of Phenothrin*.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration and Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously indentified and required the submission of generic (i.e., active ingredient-specific) data required to support reregistration of products containing the active ingredient phenothrin. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing phenothrin.

Based on the data, the Agency has sufficient information on the human health and ecological effects of phenothrin to make its decision on the reregistration process under FIFRA. The Agency has determined that products containing phenothrin will be eligible for reregistration provided that (i) required product specific data are submitted; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Needed label changes and language are listed in Section V. Appendix A summarizes the uses of phenothrin that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of phenothrin, and lists the submitted data that the Agency found acceptable.

Based on its evaluation of phenothrin, the Agency has determined that products containing phenothrin, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of phenothrin. If all changes outlined in this document are incorporated into the product labels, then all current risks of concern for phenothrin will be adequately mitigated for the purposes of this reregistration determination under FIFRA.

B. Public Comment Period

Via the public participation process, EPA worked with stakeholders and the public to reach a regulatory decision for phenothrin. EPA released the phenothrin preliminary risk assessments for public comment on March 14, 2008, for a 60-day public comment period (Phase 3 of the public participation process). The public comment period on the risk assessments closed on May 13, 2008. The Agency received comments from the registrant McLaughlin Gormley King Co. (who commented jointly with their partner registrant, Sumitomo Chemical, Ltd.), Bengal Products, Inc., and Clarke Mosquito Control Products, Inc. Comments were also received from the California Regional Water Quality Control Board of the San Francisco Bay Region, the Los Angeles Water Sanitation District, and California Tri-TAC, which represents several statewide water sanitation districts in California. The Agency also received comments from the American Mosquito Control Association and from private citizens. These comment letters in their entirety, the response to comment documents, and the preliminary and revised risk assessments can be viewed in the public docket (EPA-HQ-OPP-2008-0140) at http://www.regulations.gov.

C. Regulatory Position

a. Human Health Risk Mitigation

As outlined in Chapter 3, dietary and drinking water exposures from the pending use of mosquito adulticide applications over cropland do not result in risks of concern from phenothrin exposures. The establishment of tolerances and registration amendment of the pending use will be dealt with in a separate Agency action.

Also as cited in Chapter 3, residential exposures to adults or children did not result in risks which were above the Agency's levels of concern. Additionally, no aggregate assessment of food, drinking water and residential exposures are appropriate because the toxicity endpoints are different for dietary and residential exposures.

For the occupational assessments, (as indicated in the discussion of human health risks in Section III), human health risk estimates indicated only one occupational use scenario of concern (MOE < 1000) for the occupational handler scenario of mixing, loading, and applying liquids with a high pressure wand in a greenhouse, at the maximum use rate.

The MOE for the greenhouse mixing/loading/applying scenario was of concern without a respirator; however, the exposures were not of concern at maximum use rates with the use of PF5 respirator. No other occupational use scenarios present risks of concern.

Registrants are required to amend labeling to require the use of PF5 respirators for all high pressure hand wand applications in greenhouses. See Section V, **Table 11** for the amended labeling language.

b. Ecological Risk Mitigation

The potential ecological risks described in the *Environmental Fate and Effects Assessment* result from the widespread broadcast applications of phenothrin which employ ULV sprays. Broadcast ULV applications are typically undertaken by county and state mosquito control districts for public health purposes. It was necessary, therefore, for the Agency to weigh the public health benefits of maintaining the current use pattern of ULV applications against the potential for ecological risks. The Agency believes that reducing the application amounts or rates used in phenothrin ULV sprays will reduce its effectiveness as a public health pesticide. Therefore, the Agency will not be reducing either the labeled maximum single use rate or the number of applications allowed per year in order to mitigate ecological risks.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *"may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, phenothrin may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species.

When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of phenothrin "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for phenothrin result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing phenothrin. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that products containing phenothrin are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request a time extension and/or waiver requests with a full written justification. For the product-specific data, the registrant will have eight months to submit data. Additionally, below are the label amendments that the Agency intends to require for phenothrin in order to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of phenothrin for currently registered uses has been reviewed and determined to be substantially complete. Neurotoxicity studies which may allow the Agency to remove the 10x safety factor have been required; the registrant requested waivers for these studies and the Agency will consider these waivers.

The Agency is requiring the Photodegradation in Soil study as confirmatory data.

Environmental Fate
835.2410 Photodegradation in Soil

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table **11**.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria, and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrant's Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement the measures outlined in Section IV above. Specific language to incorporate these changes is laid out in Table 12. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. The specific time frames for existing stocks will be established on a case-by-case, however, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

Summary of Labeling Changes for All Phenothrin		
Table 11. Summary of Labeling Changes for All Phenothrin[2]		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an insecticide for the following use(s): [fill blank only with those uses that are being supported by MUP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate specific use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements	"ENVIRONMENTAL HAZARD" "This pesticide is highly toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements
End Use Products Intended for Occupational Use (WPS and non-WPS)		

[2] For products with both occupational and consumer homeowner uses, the more restrictive language from these labeling tables must be used.

PPE Requirements for Ready to Use Formulations (RTU Liquids and Pressurized Liquids) (Except for Applications with High Pressure Hand wands in Greenhouses)	PPE Requirements for Ready to Use Formulations (RTU Liquids and Pressurized Liquids) "Personal Protective Equipment (PPE)" "Some materials that chemically-resistant to this product are [registrant inserts correct material(s)]. For more options, follow the instructions for category [insert A, B, C, D, E, F. G, or H] on the chemical resistant category chart. "Applicators and other handlers must wear: > Long-sleeve shirts and long pants, and > Shoes plus socks	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Liquid Concentrates including Emulsifiable Concentrates (Except for Applications with High Pressure Hand wands in Greenhouses)	"Personal Protective Equipment (PPE)" "Some materials that chemically-resistant to this product are [registrant inserts correct material(s)]. For more options, follow the instructions for category [insert A, B, C, D, E, F. G, or H] on the chemical resistant category chart. "Applicators and other handlers must wear: > Long-sleeve shirts and long pants, and > Shoes plus socks	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Applications with High Pressure Hand wands in Greenhouses	"Personal Protective Equipment (PPE)" "Some materials that chemically-resistant to this product are [registrant inserts correct material(s)]. For more options, follow the instructions for category [insert A, B, C, D, E, F. G, or H] on the chemical resistant category chart. "Applicators and other handlers must wear: > Long-sleeve shirts and long pants, and > Shoes plus socks > PF5 Respirator when mixing, loading, and applying Liquid Concentrates including Emulsifiable Concentrates at the Maximum Use Rate Identified on the Product Label."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If not such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box).
Environmental Hazards Statements for Products Labeled for Outdoor Uses (PR Notice 2005-1 recommends separating labels intended for wide area mosquito adulticide applications.)	"ENVIROMENTAL HARZARDS" "This pesticide is toxic to fish and aquatic invertebrates. Do not apply to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate." "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the area." "Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist."	Precautionary Statement: Hazards to Humans and Domestic Animals
Environmental Hazard Statements for Products Labeled for Indoor Uses Only	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. See Directions for Use for additional precautions and requirements."	Precautionary Statements: Hazards to Humans and Domestic Animals

	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."	
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the application area during application."	Place in the Directions for Use directly above the Agricultural Use Box
General Application Restrictions for products with WPS and non-WPS uses on the label AND that are labeled for use when people may be present	**Products labeled for use as a directed spray (does not apply to products applied to domestic animals):** "Do not enter or allow others to enter treated area until sprays have dried." **Products labeled for use as a space spray:** "Do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated areas have been thoroughly ventilated." **Total release foggers labeled for indoor use must contain the following entry restriction:** Wait two (2) hours after application, and then open windows, vents, and doors for two hours. If an odor is still detected additional ventilation is required." Note to registrant: If you have any information that justifies a change in the duration after application (2 hours), submit the information to the Agency. **For applications to food/feed handling and service areas:** "Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where foods are served, such as dining rooms, but excluding areas where foods may be prepared or held. In the home, cover all food processing surfaces and	If no WPS uses are on the product label, place the appropriate statement in the Directions for Use under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.

	utensils during treatment or thoroughly wash utensils before use. Cover exposed food and remove utensils in serving areas."	
End Use Products Primarily Used by Consumers/Homeowners		
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" "This product is highly toxic to fish and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas." "This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the area."	Precautionary statements under Environmental Hazards
Entry Restrictions	"Do not allow adults, children, or pets to enter the treated area until sprays have dried."	Directions for Use under General Precautions and Restrictions
Entry Restrictions Entry Restrictions are for products applied as a spray, labeled for use as a directed spray (does not apply to products applied directly to domestic animals), as a space spray, and total release foggers labeled for indoor use must contain the following entry restrictions	"Do not enter or allow others to enter the treated area until the sprays have dried." "Do not allow people or pets to enter treated areas until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated." "Wait two (2) hours after application, then open windows, vents and doors for two hours. If an odor is still detected, additional ventilation is required." "Remove pets, birds, and cover fish aquariums and ornamental fish ponds before spraying, and turn aquarium systems off." Note to registrant-If you have any information that justifies a change in the duration after application (2 hours), submit the information to the Agency. "Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is operation. Serving areas are areas where food is served, such as dining rooms, but excluding areas where foods may be prepared or held. In the home, cover all food processing surfaces and utensils during treatment or thoroughly wash utensils before use. Cover exposed food and remove utensils in serving areas."	

General Application Restrictions	"Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift."	Place in the Directions for Use

Appendix A. Non-Food and Non-Feed Use Patterns Subject to the Reregistration of Phenothrin

Product Type	Product Use Site	Max % A.I.	Max AR
Occupational Uses			
PRL	Non-food Crops-Greenhouses	1	0.08 lb a.i./gal
PRL	Indoor Commercial and Domestic Structures, Premises, and Equipment: Surface, Crack, and Crevice Application	3	0.25 lb a.i./1000 sq. ft
PRL	Indoor Commercial and Domestic Structures and Premises and Equipment: Space Application	3	0.25 lb a.i./1000 sq. ft
PRL	Outdoor Commercial, Recreational, and Domestic Outdoor Sites. Agricultural/Farm Structures and Equipment	1	0.08 lb a.i./gal
SC/L*RTU EC*RTU SC/L	Mosquito Abatement/Adulticide-Commericial, Recreational, and Domestic Outdoor Sites	2	0.0036 lb a.i/Acre
EC	Direct Application to Pets	0.3	0.0015 lb a.i./application
PRL	Airplane Cargo Holds	10	0.8 g a.i./1000 cu. ft.
Residential Uses			
EC, PRL	Indoor Household Sprays-Space Spray	3	10 sec. spray 1.5 g/sec (0.002 lb a.i./application)
PRL	Indoor Household Sprays-Surface/Crack and Crevice Spray	3	One 16 oz. can (0.03 lb a.i./sq. ft)
SC	Indoor Household Carpet Powder	0.5	1 lb/108 sq. ft. (0.000046 lb. a.i./ sq ft.)
EC	Total Release Fogger	2	One 5 oz. can/8000 cu ft. (0.0008 lb. a.i. cu. ft.)
PRL	Outdoor House and Garden Sprays	0.2	3 sec./ cu yd. at 1.5 g/sec.
EC	Direct Application to Pets-Spot On Treatment	85.7	0.09 fl. oz. per 6000 cm^2 (2230 mg. a.i/animal)
EC, PRL	Direct Application to Pets-Spray	0.26	Half 16 oz. can/animal (590 mg. a.i./animal)

FORMULATION CODES

EC: Emulsifiable Concentrate
EC * RTU: Emulsifiable Concentrate formulated as Ready-To-Use
PRL: Pressurized Liquid
SC/L: Soluble Concentrate/Liquid
SC/L * RTU: Soluble Concentrate/Liquid formulated as Ready-To-Use

Appendix B. Data Supporting Guideline Requirements for Phenothrin

Data Supporting Guideline Requirements for the Reregistration of Phenothrin		
Guideline Number	**Study Description**	**Citation(s)**
PRODUCT CHEMISTRY		
830.1550	Product Identity and Composition	00137673, 41024601, 00054518, 40503301
830.1600	Description of Materials Used	00108532, 00121259, 00137673
830.1620	Description of Production Process	40552401, 40520601, 41246901
830.1670	Discussion of Formation of Impurities	41024601, 41246901
830.1700	Preliminary Analysis	41009701
830.1750	Certified Limits	00108532, 000121259
830.1800	Analytical Method	41009701, 40503401, 44085402
830.6302	Color	41009702, 00054518
830.6303	Physical State	41009702, 00054518
830.6304	Odor	41009702, 00054518
830.6313	Stability	41009702, 00054518
830.7000	pH	41009702, 00054518
830.7050	UV/Visible Absorption	**Data Gap**
830.7300	Density	41009702
830.7550 830.7570	Octanol / Water Partition Coefficient	41009704, 41009706
830.7840 830.7860	Solubility	41009705, 00067405
830.7950	Vapor Pressure	41009707
ECOLOGICAL EFFECTS		
850.1010	Aquatic Invertebrate Acute	44407901, 000121276
850.1025	Oyster Acute Toxicity Test	44587001
850.1035	Mysid Acute Toxicity Test	44388801
850.1075	Fish Acute Toxicity	
	Freshwater	40908307, 40908308
	Estuarine / Marine	44388901, 44388902
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	44407901, 44587003
850.1350	Aquatic Invertebrate Life Cycle (Marine)	44388903
850.1400	Fish Early Life Stage (Freshwater and Marine)	44587002
850.1730	Fish BCF	41393901, 42774301
850.2100	Avian Acute Oral Toxicity	121277, 121275, 40908306
850.3020	Honey Bee Acute Contact Toxicity	41173401
EXPOSURE ASSESSMENT		
Special Study	Review of Non-Dietary Exposure	46188602, 46188613, 46188623, 46188629

	Task Force Studies	
Special Study	Residential Joint Venture National Pesticide Use Survey	46099001
TOXICOLOGY		
870.1100	Acute Oral Toxicity	40908302
870.1200	Acute Dermal Toxicity	40908303
870.1300	Acute Inhalation Toxicity	43889301
870.2400	Acute Eye Irritation	40908304
870.2500	Acute Dermal Irritation	40908304
870.2600	Skin Sensitization	40908305
870.3100	90-Day Oral Toxicity in Rodents	40998202
870.3200	21/28 -Day Dermal Toxicity	41009710
870.3465	90-Day Inhalation Toxicity	41289201
870.3700	Prenatal Developmental Toxicity	41230003, 47452201
870.3800	Reproduction and Fertility Effects, 2-Generation Reproduction	40276404, 44082201
870.4100	Chronic Toxicity	40276405, 40276401
870.4200	Carcinogenicity	40276402
870.4300	Combined Chronic Toxicity/Carcinogenicity	43927001
870.5265	Gene Mutation (Ames assay)	00148559
870.5385	Bone Marrow Chromosomal Aberration Test	00148561
870.5550	Unscheduled DNA Synthesis in mammalian cells in culture	00160489
870.6200	Neurotoxicity Screening battery	
(a)	Acute Neurotoxicity	**Data Gap**
(b)	Subchronic Neurotoxicity	**Data Gap**
870.6300	Developmental Neurotoxicity Study	**Data Gap**
870.7485	Metabolism and Pharmacokinetics	40276403
ENVIRONMENTAL FATE		
835.1230	Leaching and Adsorption / Desorption	46740602, 46740601, 46740601
835.1410	Laboratory Volatility	Waived
835.2120	Hydrolysis	46080102, 45412002, 46104501, 45412001, 41958201
835.2240	Photodegradation in Water	41898805
835.2370	Photodegradation in Air	Waived
835.2410	Photodegradation in Soil	**Data Gap**
835.4100	Aerobic Soil Metabolism	42085101, 42238001, 42085102, 42238002
835.4300	Aerobic Aquatic Metabolism	44865902
835.4400	Anaerobic Aquatic Metabolism	44865901
835.6100	Terrestrial Field Dissipation	42895901, 42895902
835.7100	Ground Water Monitoring	Waived
835.8100	Field Volatility	Waived

Appendix C. Technical Support Documents

Additional documentation in support of the phenothrin RED is maintained in the OPP Regulatory Public Docket, located in Room S-4400 One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP Docket room or viewed and/or downloaded via the Internet at http://www.regulations.gov. The Agency's documents in support of this RED include the following:

1.) Daiss, B. Revised Risk Assessment for the Reregistration Eligibility Decision for Phenothrin. July 2, 2008.

2.) Daiss, B. Revised Occupational and Residential Exposure for the Reregistration Eligibility Decision for Phenothrin. July 2, 2008.

3.) Melendez, J. d-Phenothrin (Phenothrin) Acute and Chronic Dietary and Drinking Water Exposure and Risk Assessment for the Reregistration Eligibility Decision. February 6, 2008

4.) Melendez, J. and Woodard, V. Environmental Fate and Effects Science Chapter for the Reregistration Eligibility Decision of Phenothrin.

Appendix D. Bibliography

In addition to the studies listed in Appendix B, this bibliography contains additional citations considered to be part of the database supporting the reregistration decision for phenothrin.

In addition to the MRID study references listed in Appendix B, this bibliography contains the expanded study citations as well as additional literature considered to be part of the database supporting the reregistration decision for phenothrin.

MRID	Citation
41009702	Nakazawa, H. (1989) Sumithrin: Color, Physical State, Odor, Specific Gravity, pH, Stability & Flammability. Unpublished study prepared by Biochemistry and Toxicology Laboratory. 24 p.
41009704	Saito, S. (1989) Sumithrin: Water Solubility & Partition Coefficient (Octanol/Water). Unpublished study prepared by Biochemistry and Toxicology Laboratory. 29 p.
41009705	Duescher, R.; Loken, R. (1989) Determination of Solubility of Sumithrin in Organic Solvents: Final Report: Proj. ID HLA 6001-264B. Unpublished study prepared by Hazleton Laboratories America, Inc. 16 p.
41009707	Semann, T. (1989) Vapor Pressure Determination of Sumithrin: Final Report: Study No. 6001-260. Unpublished study prepared by Hazleton Laboratories America, Inc. 23 p
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